Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

DATE: July 28, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Nutracoastal Trading LLC Recall

SUGGESTED ACTION: **Unclassified Recall; STEAM Dietary supplement lot 80214; Information provided in case of consumer inquries.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The recalled product listed below was distributed in white plastic bottles to retail stores nationwide. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

****

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nutracoastal Trading LLC conducts voluntary nationwide recall of STEAM Dietary supplement lot 80214

Consumer contact:
David McLoughlin
866-803-2434

FOR IMMEDIATE RELEASE - Freeport, NY - July 28, 2009 - Nutracoastal Trading LLC announced today that it is conducting a voluntary nationwide recall of the company's dietary supplement product sold under the following name: **STEAM**.

The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA for Lot 80214 found that the product contains sulfoaildenafil, an analog of sildenafil. Sildenafil is an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making **STEAM DIETARY SUPPLEMENT** an unapproved drug. The active drug ingredient is not listed on the product label. The undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

The recalled product listed below was distributed in white plastic bottles to retail stores nationwide.

Brand Name	**Size**	**Lot**	**UPC**
STEAM	1 Bottle - 5 Capsules	80214	8 52263 30033 1

No illnesses have been reported to the company to date in connection with this product.

Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Nutracoastal Trading LLC, a Delaware Limited Liability Company, is committed to providing accurate information about its products because of concerns for the health and safety of consumers. Nutracoastal Trading LLC is working voluntarily with the FDA in the recall process. It sincerely regrets any inconvenience to customers.

Consumers should return any unused product to the retail location where they were purchased or contact Nutracoastal Trading LLC directly at 866-803-2434 Monday - Friday, 9 am to 5 pm EDT.

###